UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:
All Cases

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS ENGINEERING EXPERTS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

Regulations

INTRODUCTION

This litigation is about patients who suffered periprosthetic joint infections (ñPJIò) caused by airborne particles laden with bacteria. Specifically, this case is about Defendantsô Bair Hugger Forced Air Warming system (ñBair Huggerò) device being the most likely cause of moving those bacteria-laden airborne particles into the sterile field to cause the severe periprosthetic joint infections.

To be relevant for purposes of Federal Rule of Evidence 702, expert testimony must be related to the determination of a fact issue. But no rule and no binding case requires that any one expertôs testimony directly answer the ultimate question.

Each of Plaintiffsô experts disclosed opinions and findings that explain a portion of Plaintiffsô case. Link-by-link, Plaintiffsô experts use reliable methodology in arriving at their opinions on issues within their relative expertise, ultimately fashioning a chain identifying Bair Hugger as the cause of periprosthetic joint infections. Defendantsô complaint that Plaintiffsô experts ñcould haveò conducted some other kind of testing is not a basis to exclude the testing that Plaintiffsô experts actually performed and the opinions that follow from that testing.

This is particularly true in light of evidence that establishes the link between particles and bacteria. As Plaintiffs explain in their response to Defendantsô motion for summary judgment[1] Defendantsô own documents and experts admit that up to 40% of

[1] (Doc. No. 672)

airborne particles carry bacteria.[2] Given those concessions, there is no ñanalytical gapò between Plaintiffsô expertsô testing regarding airborne particles and their conclusions regarding the bacteria carried by those particles that would justify, much less require, exclusion of Plaintiffsô engineering experts.

I. FACTUAL BACKGROUND

A. Bair Hugger Increases Particles Over the Sterile Field is Not in Dispute

Plaintiffsô experts and most, if not all, of Defendantsô experts agree that: (1) bacteria cause PJIs; (2) an increase in bacteria in the sterile filed increases the incidence of PJIs; (3) the increase of particles is directly correlated with increased bacteria over the sterile field; (4) and the Bair Hugger increases particles over the sterile field.[3]

Bair Hugger increases particles over the sterile field. 3M admits that all studies, even internal studies, show increased particles over the sterile field:[4]

[2] Ex. 1, Wenzel Dep. (50:2-15). All references to Ex. __ are references to exhibits to the Declaration of Genevieve M. Zimmerman in Support of Plaintiffsô Response Opposing Defendantsô Motion to Exclude the Opinions and Testimony of Plaintiffsô Engineering Experts, filed concurrently herewith.

[3] (*See* Plaintiffs Opposition to Defendantsô Motion for Summary Judgment).

[4] Ex. 2, 30(b)(6) Dep. (258:5-13).

Q. Okay. Based on the data that we have today, including the study funded by 3M as well as other studies, every single study indicates that the Bair Hugger increases the particle count over the sterile field; correct?

A. In absolute numbers, yes.

Q. Yes. Okay. And you have no internal studies to refute that; correct?

A. No, we don't.

This dangerous defect is not news to 3M. 3M and Arizant have been aware since at least June 23, 2007, that intraoperative warming contaminates the sterile filed and transmits nosocomial pathogens.[5] Perhaps the knowledge of the danger of Bair Hugger in the OR is what prompted 3M to refocus its marketing on their pre-warming product, ñBair Paws.ò ñPre-warmingò is the process of warming the patient prior to the patient being brought into the surgical suite, as opposed to warming the patient during the surgical procedure.

3M created the following chart[6] describing the relative advantages and disadvantages of pre-warming over intra-operative warming:

[5] Ex. 3, Clinical Trial Protocol of Bair Paws authored by Al Van Duren, Director of Clinical Affairs and Defendants 30(b)(6) witness (3MBH00982867-85).
[6] *Id.* at 3MBH00982878.

Advantages	Disadvantages

Table 1 – Advantages and disadvantages of convective prewarming

As the chart indicates, Defendants knew that that the advantages of Bair Paws over Bair Hugger include safety, use in orthopedic cases, and avoiding contamination of sterile field, surgical site infections, and nosocomial transmission of pathogens.

Dr. Said Elghobashi performed a computational fluid dynamics (ñCFDò) analysis which revealed exactly what 3M already knew: Particles over the sterile field increase when Bair Hugger intraoperative warming is used.[7] Dr. Elgohbashiôs CFD shows that when the Bair Hugger is off, the HVAC system acted as it was supposed to and prevented 10 µm particles from reaching the sterile field.[8] However, when the Bair Hugger was turned on, an exponential number of squames (10 µm particles) reached the surgical

[7] Ex. 4 (Elghobashi Report).
[8] *Id.*

wound, the patient, and the table where the implant and other surgical tools are located during the procedure.[9]

Defense Expert Thomas Keuhn, another Ph.D. engineer, agreed with Dr. Elghobashiôs model ñthat particles under the operating table and/or on the floor of the operating room can be transported to the surgical site by use of the Bair Hugger.ò[10] To engineers, the conclusion that the Bair Hugger causes increased particles over the sterile field is obvious in light to well-established engineering principles. Even to an infectious disease doctor such as Dr. Wenzel, the idea that that the Bair Hugger causes air currents is a no-brainer.[11] 3Môs funded study likewise confirmed that particles increased over the surgical site when the Bair Hugger is turned on.[12]

B. Studies Also Conclude that the Bair Hugger Increases Bacterial Density Over the Sterile Field

A recent study by Oguz et. al. (not associated with Augustine) indicates that the presence of the Bair Hugger increased the bacterial load at the surgical site by 55%.[13] Moretti et. al. also demonstrated an increased bacterial load in an OR when the Bair Hugger was in use, as compared to when the OR was at rest.[14]

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[9] *Id*.
[10] Ex. 5, Keuhn. Depo. (324:5-12).
[11] Ex. 1, Wenzel Dep. (147:15-24).
[12] Ex. 6, Sessler DI, Olmsted RN, Kuelpmann R. *Forced-Air Warming Does Not Worsen Air Quality In Laminar Flow Operating Rooms*. ANESTH ANALG. 113(6):1416-21
[13] Ex. 7, Oguz, Ruken et al., *Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial*, J CLIN ANESTH , Volume 38 , 160 ï 164.
[14] Ex. 8, Moretti B, Larocca AMV, Napoli C, et al. *Active Warming Systems To Maintain Perioperative Normothermia In Hip Replacement Surgery: A Therapeutic Aid Or A Vector Of Infections*? J HOSP INFECT (2009); 73:58-63.

C. Instead of Research, 3M Utilizes Marketing and Disparagement Techniques Against Anyone Who Questions the Safety of the Bair Hugger

3M decided ñat the highest levelò not to conduct any clinical trials on the safety and efficacy of the Bair Hugger.[15] The decision not to do safety or verification testing was one in a long line of Defendantsô decisions not to conduct any testing, dating back to the development of the first version of Bair Hugger designated for use in an operating room, the Bair Hugger Model 505 (the previous version specifically warned against use in the operating room).[16] Instead of conducting clinical trials, 3M used its massive financial resources to attack studies suggesting the Bair Hugger was potentially not safe and conduct studies over which they had editorial control.[17] 3M has created numerous websites and a Wikipedia page, and it has also utilized its outside counsel, Blackwell Burke, to host websites promoting safety of the Bair Hugger, and attacking studies, documents, and even prominent academics that raise safety questions.[18]

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[15] Ex. 9, (3MBH01330587) (Email from Morken to Waite dated July 10, 2015).

[16] Ex. 2, 3M 30(b)(6) witness Al Van Duren confirmed that Defendants did not conduct any biological testing during the development of the Bair Hugger 505 and likewise was unable to recall any biological testing during development of the next generation device, the 750. Ex. 2 (48:13-18; 51:5-16; 86:16-89:20). Another 3M witness, Carl Zgoda, the project leader for the 750, [redacted] Ex. 44, Dep. of Carl Zgoda (42:22-43:5). The predicate device to Augustineôs original Bair Hugger invention was a 1937 ñcast warmer.ò *See* Ex. 45.

[17] *See, e.g.*, Ex. 46 (3MBH00083780); Ex. 47 (3MBH00544754); Ex. 18 (3MBH01224622).

[18] Blackwell Burke registered the domains www.truthaboutbairhugger.com and www.bairhuggerfatcs.com. (Ex.10 and 11). The domains recently changed ownership to 3M.

3Môs attempts to misdirect the Courtôs attention by pointing the finger at Augustine.[19] These attacks may influence an uninformed reader, but should not have an influence in a court of law where methodology and reliability of scientific principles apply.

As outlined in Plaintiffsô opposition to Defendantsô Motion for Summary Judgment, many of Defendantsô experts agree with Plaintiffsô experts regarding each step of the mechanism of defect and injury in this case. 3M argues with scientific principles, suggesting fundamental scientific and medical principles must be false if Augustine agrees with them. But Augustine did not invent the Law of Thermodynamics, or the equations of fluid dynamics and heat transfer, and he did not create the *Navier-Stokes* equations upon which both Dr. Elghobashi and Dr. Abraham aver reliance for their respective computer simulations. Augustine did not create the concept of buoyancy or the fact that hot air rises, nor did he create turbulence, which disrupts unidirectional airflow.

3M cannot blame Augustine for the 3M particle study that indicated that the Bair Hugger increases particles in the sterile field.[20] Augustine did not force the Defendantsô expert Dr. Keuhn to admit that, based on engineering and scientific principles, particles on the floor or below the operating room can be transported to the surgical site by use of the Bair Hugger.[21]

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[20] Ex. 6 (Sessler Study).
[21] Ex. 5, Kuehn Dep. (324:5-12).

Augustine did not manufacture the equipment that measured particle counts and he did not invent the neutrally buoyant bubbles that demonstrated an increase over the sterile field when the Bair Hugger is used in both the 3M study and other studies.[22] Augustine did not create the thermocouples that measured the increase in temperature over the sterile field when the Bair Hugger is on.[23] Having put its head in the proverbial sand, 3M has steadfastly engaged in a slander campaign and series of flawed studies to confuse the Court, the jury, and the public.

D. Dr. Scott Augustine Is Not Involved in This Case

Augustine has no control over this case. Augustine is not directing this litigation, nor was he directly or indirectly involved in any of the work conducted by Plaintiffsô

[22] *See* Ex. 11, Darouiche, R., Green, D., Harrington, M., Ehni, B., Kougias, P., Bechara, C., & OôConnor, D. (2017). *Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial*. INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY, 38(1), 3-10. doi:10.1017/ice.2016.240); Ex. 12, Legg, Cannon, and Hamer, *Do forced air patient warming devices disrupt unidirectional downward airflow?,* THE JOURNAL OF BONE AND JOINT SURGERY (2012); Ex.13, Legg and Hamer *Forced-air patient warming blankets disrupt unidirectional airflow,* THE JOURNAL OF BONE AND JOINT SURGERY (2013); Ex. 14, Kumar Belani, MBBS, MS, Mark Albrecht, MStat, MBA, BSME, Paul D. McGovern, BSc, MBBS, MRCS, PGCME, FHEA, Mike Reed, MBBS, MD, FRCS, (T&O), and Christopher Nachtsheim, PhD, *Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance*, ANESTHESIA & ANALGESIA (2012); Ex. 15, P.D. McGovern, et. al. *Forced-air warming and ultra-clean ventilation do not mix*, THE JOURNAL OF BONE & JOINT SURGERY (November 2011).

[23] *See* Ex. 16, Brandt, Oguz, Huttner, et al, *Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients*, ANESTHESIA-ANALGESIA (March 2010); Ex. 17, K.B. Dasari, M. Albrecht, and M. Harper, *Effect of forced-air warming on the performance of operating theatre laminar flow ventilation*, ANAESTHESIA (2012).

engineering experts. Augustine is not a real party in interest. Nor is he controlling the thousands of injured people whose cases have been consolidated into this MDL.

This Court should not countenance 3Môs continued injection of its interminable Augustine soap opera into this MDL. It is offensive to the people injured by Bair Hugger. It is offensive to the world class experts who conducted tests and research to evaluate the link between Bair Hugger and infections. It is offensive to the members of this bar whose firms have spent thousands of hours and hundreds of thousands of their own dollars to evaluate and prosecute this case. Defendantsô efforts to muddy the waters with tales of Augustine this and Augustine that is in truth an attempt to keep this Court and the medical community at large from focusing on the dangers associated with the Bair Hugger, and prevent recognition that 3Môs scientifically bankrupt product is maiming and even killing patients by depositing bacteria-laden particles into open surgical incisions. At some point, 3M should put up or shut up. If Augustineôs conduct is tortious, if the allegations he made are baseless, then 3M should sue him. Either way, the time has come for 3M to stop clouding the issues in this MDL with personal animus towards Augustine.

II. LEGAL STANDARDS

A. *Daubert* And Rule 702 Favor The Admissibility Of Expert Testimony

The Federal Rules of Evidence embrace a general approach of relaxing the traditional barriers to opinion testimony and embody a governing principle favoring admissibility. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587-88 (1993) (citing Federal Rule of Evidence 401, 402, and 702). Expert testimony is admissible under Rule

702 if: (1) the reasoning or methodology underlying the testimony is scientifically valid (the ñreliabilityò prong); and (2) the reasoning or methodology can properly be applied to the facts in issue (the ñrelevancyò prong). *Id.* at 592-93. The trial court must make a preliminary determination that expert testimony is both reliable and relevant before it may be admitted. *Id*. at 581. Pertinent evidence based on scientifically valid principles will satisfy those demands. *Id.* at 597.

Daubert identified four non-exclusive factors to consider in assessing whether scientific evidence is reliableð none of which, alone, is determinative: (1) whether the scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether a particular technique has a known potential rate of error; and (4) whether the theory or technique is accepted in the relevant scientific community. *Id.* at 593-94. That the research relied on by experts is accepted for publication in a scientific journal after being subjected to the usual rigors of ñpeer reviewò is a significant indication that it meets at least the minimal criteria of good science. *Id.* at 593.

The Eighth Circuit and other courts have identified additional factors for admissibility, including whether the experts are proposing to testify about matters growing naturally and directly out of research they have concluded independent of the litigation.ò *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317-18 (9th Cir. 1995) (ñ*Daubert II*ò); *see also Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 687 (8th Cir. 2001) (adopting *Daubert II* factor). Experts satisfy this criterion if they can explain ñhow they went about reaching their conclusions and point to some objective source ï a learned

treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like ï to show that they have followed the scientific method, as practiced by (at least) a recognized minority of scientists in their field.ò *Daubert II*, 43 F.3d at 1318-19.

Scientific evidence is reliable if it is based on an assertion that is grounded in methods of science. *Daubert*, 509 U.S. at 590. The focus is on principles and methodology, not conclusions. *Id*. at 596. It is unreasonable to require the subject of scientific testimony to be ñknownò to a certainty, since science is an evolving process and ñthere are no certainties in science.ò *Id*. at 590.

The Supreme Court has recognized that there is a range in which experts might reasonably differ on issues of science, and that such conflicting evidence should be admitted to aid the jury in deciding those issues. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999); *see also Johnson v. Mead Johnson*, 754 F.3d 557, 564 (8th Cir. 2014) (ñ[T]he jury, not the trial court, should be the one to decide among the conflicting views of different experts.ò).

Rule 702 codified the *Daubert* standard in its 2000 amendment. Fed. R. Evid. 702 advisory committee note (2000). As the Advisory Committee made clear, the exclusion of expert testimony ñis the exception rather than the ruleò and the trial courtôs gatekeeper role ñis not intended to serve as a replacement for the adversary system.ò *Id.*

B. Eighth Circuit Authority follows *Daubert's* flexible approach to the Admissibility of Expert Testimony.

The Eighth Circuit has remained ñconsistently loyalò to the language of *Daubert* and Rule 702. *Lauzon*, 270 F.3d at 687 n.2. The ñcases are legion that, correctly, under *Daubert*, call for the liberal admission of expert testimony.ò *Johnson*, 754 F.3d at 562. Rule 702 is clearly ñone of admissibility rather than exclusion.ò *Lauzon*, 270 F.3d at 686. ñThe exclusion of an expertôs opinion is proper only if it so fundamentally unsupported that it can offer no assistance to the jury.ò *Wood v. Minnesota Mining and Mfg. Co.*, 112 F.3d 306, 309 (8th Cir. 1997).

The Eighth Circuit instructs that proponents of expert testimony need not prove that their expertsô conclusions are correct. *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012). It also admonishes that ñtrial courts are not empowered to determine which of several competing scientific theories has the best provenance.ò *Id.* at 633. A district court therefore abuses its discretion if it resolves doubts in favor of excluding expert testimony and decides for itself the correctness of the expert opinion. *Johnson*, 754 F.3d at 562.

ñAs a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility.ò *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995). Rule 702 does not demand that a causation opinion be based on a ñscientific absoluteò to be admissible. *Adams v. Toyota Motor Corp.*, 867 F.3d 903 (8th Cir. 2017). Flaws in an expertôs methodology, or the novelty of the conclusions, do not warrant exclusion of the expertôs testimony. *Bonner v. ISP Technologies, Inc.*, 259 F.3d

924, 929 (8th Cir. 2001); *Johnson*, 754 F.3d at 564.[24] Limitations of data relied on by the expert instead go to the weight a jury gives the testimony. *Hose*, 70 F.3d at 974. Likewise, the fact that an expertôs conclusion has not yet been accepted by the scientific community does not bar the opinionôs admissibility. *Bonner,* 259 F.3d at 932.

As long as the expertôs testimony rests on ñgood grounds, based on what is known,ò disputes as to the basis for an expertôs opinion are for the jury to decide: ñVigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.ò *Daubert*, 509 U.S. at 596; *Johnson*, 754 F.3d at 562. In the Eighth Circuit, the rejection of expert testimony ñis the exception rather than the rule.ò *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006).

C. ***Daubert*** **Does Not Impose a Higher Standard for Engineers**

Daubert's analysis applies equally to *all* types of expertsð whether they are expressing opinions on scientific or other technical knowledge. *Kumho Tire Co.*, 526 U.S. at 149. The same flexible standard under Rule 702, which admits testimony with a reliable basis in knowledge or experience, grants that latitude ñto all experts, not just to óscientificô ones.ò *Id.* at 148. As long as the testimony falls within the ñrange where experts might reasonably differ,ò it should not be excluded. *Id.* at 153; *Johnson*, 754 F.3d at 564. To demand that testimony be based on a ñconvincingò or definitive level of

[24] For example, in *Johnson*, the Eighth Circuit found that the plaintiffôs expertôs incomplete testing and failure to consider potential confounding factors did not undermine the reliability of his testimony; it was up to the jury to determine whether his conclusions were correct. *Johnson*, 754 F.3d at 564.

evidence where reasonable experts can disagree on whether a statistical association is causal ñwould set a separate, higher standard for scientists than for other witnesses with specialized knowledge.ò *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 188 (S.D.N.Y. 2005) (citing *Kumho Tire Co.*, 526 U.S. at 148).

Daubert does not expressly require testing, just testability. Under *Daubert*, the ñtestabilityò of a theory is critical to its admissibility, as ñfalsifiability, or refutability, or testabilityò is necessary to discern valid scientific opinions. *See Daubert*, 509 U.S. at 593 (citation omitted). In *Holverson v. ThyssenKrupp Elevator Corp*., Judge Montgomery followed *Daubert* and refused to exclude the opinions of the plaintiffôs expert even though the opinions were based only on ñextensive experience and undisputed mechanical engineering principles, and that his theory was indeed testableò *See* Civ. No. 12-2765 ADM/FLN, 2014 WL 3573630 at *9 (D. Minn. July 18, 2014). Although the defendantsô expert performed actual testing and obtained results at odds with plaintiffôs expertôs opinions, Judge Montgomery properly held that the ñconclusions [that] should be drawn from [defendantôs expertôs] testing of that theory is a matter for the factfinder.ò *Id.*

D. Expert Testimony "Fits" If Assumptions Are Not Inconsistent With Case Facts And Testimony Assists The Jury

Expert testimony must fit the facts of the case. Rule 702. Testimony ñfitsò the facts of the case when it is not inconsistent with undisputed facts and the expert does not leave too great an analytical gap between the data presented and the opinion rendered. *See Gen. Elec. Co., v. Joiner*, 522 U.S. 136, 146 (1997).

Disputes as to underlying facts or inputs or other ñimperfectionsò in a study do not necessarily give rise to an improper analytical gap. *See Kuhn v. Wyeth*, 686 F.3d 618, 632 (8th Cir. 2012). Nor does speculation. *See Weitz Co. v. MH Washington*, 631 F.3d 510 (8th Cir. 2011) (ñExpert opinion necessarily involves some speculation.ò).

3M argues that Plaintiffsô experts should be excluded because they did not test for bacteria at the surgical site. But expert testimony, like that of lay witnesses, is not strictly limited to ultimate issues in dispute. Evidence is relevant if it ñhas any tendency to make a fact more . . . probable than it would be without the evidenceò and ñthe fact is of consequenceò to the case. F.R.E. 401. It is not necessary that each piece of evidence prove the ultimate fact in the case. The comments to Rule 401 note, ñit is not to be supposed that every witness can make a home run.ò (internal citations omitted).

Expert testimony can be helpful to the jury even if the testimony does not directly resolve a disputed issue. *See City of Tuscaloosa v. Harcros Chemicals, Inc.*, 158 F. 3d 548, 565-66 (11th Cir. 1998). ñAs circumstantial evidence, [the expertôs] data and testimony need not prove the plaintiffsô case by themselves; they must merely constitute one piece of the puzzle that the plaintiffs endeavor to assemble before the jury.ò *Id*.

III. ARGUMENT

A. Testing for Bacteria at The Surgical Site Is Not Required

Daubert does not impose a blanket requirement to conduct testing on the ultimate fact in dispute. 3M argues (at 48) that Plaintiffsô engineering experts should be excluded because they did not test for bacteria at the surgical site. There is no support for Defendantsô requested exclusion. It is entirely acceptable for an expert to opine on an

intermediate fact (*e.g.*, Bair Hugger ejects particles, including particles 10µm or greater; Bair Hugger causes turbulent air flows that move 10µm particles over the surgical site), and then support that opinion with appropriate testing or other reliable methodologies.

3M rarely specifies the precise testimony that they claim is improper. The ñgapò identified in *General Elec. Co. v. Joiner* inherently requires comparison of a particular opinion to the data purporting to support that opinion. *See Gen. Elec. Co.*, 522 U.S. at 146 (evaluating analytical gap between data and conclusion). Without that comparison, it is impossible to evaluate whether the opinion is supported by data. To the extent 3M is arguing that Plaintiffsô experts did not support the particular opinions they offer, any exclusion or limitation should be narrowly applied to particular opinions, rather than excluding their entire disclosures as 3M has requested.

3Môs elevation of ñtestingò to a dispositive factor is at odds with *Daubert* and its progeny. *Daubert* sets forth a series of factors to be considered when evaluating admissibility of expert testimony, but they are not ña definitive checklist or test.ò *Daubert*, 509 U.S at 593. ñIt is clear the [Supreme] Court did not intend for a trial judge to automatically exclude relevant evidence if one of these conditions was not fully satisfied.ò *Jensen v. Eveleth Taconite Co.*, 130 F.3d 1287, 1298 (8th Cir. 1997). If an expert uses a reliable methodology to reach a conclusion that would provide relevant information to the jury, the expert testimony should be admitted. ñ[N]either Rule 702 nor *Daubert* requires that an expert opinion resolve an ultimate issue of fact to a scientific absolute in order to be admissible.ò *Bonner*, 259 F.3d at 929.

ñThere is no single requirement for admissibility as long as the proffer indicates that the expert evidence is reliable and relevant.ò *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005). Evidence is relevant if it ñhas any tendency to make a fact more . . . probable than it would be without the evidenceò and ñthe fact is of consequenceò to the case. F.R.E. 401. It is not necessary that each piece of evidence prove the ultimate fact in the case. As the comments to Rule 401 note, ñit is not to be supposed that every witness can make a home run.ò (internal citations omitted).

Michael Buck performed testing indicating that Bair Hugger ejects particles greater than 10µm.[25] Dr. Elghobashiôs CFD simulation shows that 10µm particles are mobilized by Bair Hugger and transported to the surgical site.[26] Because other evidence unambiguously and directly links such particles to CFUs,[27] it was enough for Plaintiffsô experts to evaluate Bair Huggerôs dramatic impact on particle movement, and 10µm particles in particular.

Despite 3Môs effort to manufacture one, there is no real ñanalytical gapò between particle analysis and CFU contamination. Dariouche recently published the results of a randomized, controlled trial and found ñairborne particle counts may be used as a proxy for ambient CFU density.ò[28]

[25] Ex. 43 (Buck Rep.).
[26] Ex. 4 (Elghobashi Rep.).
[27] *See*., *e.g*., Ex. 11 (Darouiche); Ex. 19 (Stocks); Ex. 20 (ICOS).
[28] Ex. 11 (Darouiche).

Stocks found a correlation between bacterial colony-forming-units (CFUs) and particles greater than 10µm.[29]

The International Consensus of Orthopedic Surgeons Statement said the same.[30] Dr. Wenzel, Defendantsô infectious disease expert, testified that perhaps 40% of operating room particles carry bacteria.[31] That is because the majority of the particles in the operating room that cause airborne contamination are skin squames that come from the people in the operating room at the time of the surgery. *Id*.

In fact, facing criticism in 2010 that Bair Hugger increased exposure to bacteria near surgical sites, defendants own internal tests used particles as a proxy for bacteria.[32] ñWhen a litigant clearly believes a certain methodology is acceptable as shown by his or her own expert's reliance on that methodology, it is disingenuous to challenge an opponent's use of that methodology.ò *Shuck v. CNH America, LLC*, 498 F.3d 868, 875 (8th Cit. 2007). Defendant executives Al Van Duren and Gary Hansen conducted an experiment in the Netherlands in which particles were counted near a simulated surgical site. The raw data from the first testing location showed a 5-10x increase in particle counts caused by the Bair Hugger in just five minutes.[33] The paper notes that publications

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[29] *See* 3Môs Motion at 35-36; *see also* Ex. 19, Stocks, Gregory W. et al, *Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery*, AMERICAN JOURNAL OF INFECTION CONTROL, Volume 38, Issue 3, 199 ï 204.

[30] Ex. 20, *Operative Environment, International Consensus of Orthopedic Surgeons*, J ORTHOP RES 32:S60-S80, 2014.

[31] Ex. 1, Wenzel Dep. at 50:2-15.

[32] Ex. 6 (Sessler).

[33] Ex. 21, Sessler email to Hansen (3MBH00050932).

have found that Bair Hugger does not increase bacteria dispersion, and concludes in the next sentence by claiming to ñextend these resultsé .ò[34] 3M touted that result in a press release that specifically referred to surgeonsô concerns about bacteria near the surgical site.[35]

Despite repeated urging from their consultants, Defendants have never performed a bacteriology study (or at least one that they did not withhold as privileged). The only kind of studies Defendants have performed are those that equate particles with bacteria. Having performed its own studies that equate particles with bacteria, 3M is in no position to criticize Plaintiffs for doing the same thing here.[36] As in *Shuck*, 3Môs attempt to impose a higher burden on Plaintiffs than 3M applies to its own studies should be rejected.

As the Comments to Rule 401 make clear, ñA brick is not a wall.ò (internal citation omitted). The opinions offered by Plaintiffs experts are ñbricks,ò pieces in the evidentiary wall in this MDL. The opinions are relevant under Rule 401 and ñfitò for *Daubert* purposes even if each individual expert did not attempt to fully resolve the ultimate question of whether Bair Hugger causes DJI.

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[34] *Id.*

[35] http://www.fawfacts.com/_asset/8y2q1k/Sessler-Olmsted-Release.pdf last accessed September 28, 2017.

[36] Similarly, when 3M consultant Dr. Sessler advised 3M to conduct a bacteriology study in 2013, Al Van Duren ñstrongly resisted conducting a study of this type.ò Ex. 22 (3MBH00134035); Ex. 23 (3MBH00107719). It is equally ñdisingenuousò for 3M to require plaintiffs to conduct a study that 3Môs own Clinical Director would not conduct.

Other evidence, including that evidence cited above, shows that certain particles, including particles of the size identified by Buckôs testing, can carry bacteria.[37] Plaintiffs have offered evidence, including the Large Eddy Simulation (ñLESò)[38] performed by Dr. Elghobashi, which shows that a significant number of 10µm particles are mobilized by Bair Hugger and transported to the surgical site.[39] When considered in the context of that additional evidence, Plaintiffsô expertsô testing and opinions increase the likelihood that Bair Hugger caused an infection by emitting bacteria-laden particles which increases the bioburden around the surgical table and migrate into the sterile field.

There is nothing in 702 or the Rules of Evidence that restricts expert testimony to ultimate facts. The rules of evidence permit an expert to offer testimony on an intermediate fact. For example, in *Bonner*, an expertôs opinion on the ultimate issue (chemical exposure caused permanent Parkinsonian symptoms) was excluded, but the expert was allowed to testify to an intermediate fact (exposure caused plaintiffs acute symptoms). *Bonner*, 259 F.3d at 931.

3Môs reliance on *Werth* (at 50-51) is misplaced. In *Werth v. Hill-Rom, Inc.*, an expertôs analysis was held unreliable because the expert did not comply with the requirements of the methodology the expert purported to follow. 856 F.Supp. 2d 1051, 1063-64 (D.Minn. 2012). The expert in *Werth* claimed to be following the NFPA 921 fire investigation methodology. *Id*. at 1058. 3Môs block quote shows only that the *Werth*

[37] Ex. 1, Wenzel Dep. (50:2-15).
[38] ñLESò is one of the methods used in computational fluid dynamics simulations.
[39] Ex. 4 (Elghobashi Rep.).

experts failed to determine how an ignition source reached the first fuel ignitedð an express requirement of their NFPA 921 investigation protocol. *Werth*, 856 F.Supp.2d at 1061. The failure to follow the requirements of the NFPA investigation protocol resulted in the exclusion of the proffered expert testimony. *Id.*

Another distinguishing factor is, as *Werth* pointed out, courts repeatedly recognized the importance of physical testing to validate a theory under NFPA 921.[40] *Id*. at 1063-64. Thus, *Werth* held that the experts failed to reliably apply their methodology: NFPA 921 expressly requires testing. *Id*. at 1060. Defendants have identified no equivalent testing requirement for any of the methodologies applied by Plaintiffsô engineers.

Defendantsô allegation that Dr. Elghobashi conducted a mere ñthought experiment[s]ò (at 51) notwithstanding, other jurisdictions have held that ñaé computer model is a perfectly acceptable form of test.ò *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 815 (7th Cir. 2012). Defendants are, of course, free to cross-examine Plaintiffsô experts on their choice of methodology. But even where other methods are available, ñé so long as the methods employed are scientifically valid, [] mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony.ò *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 956 (8th Cir. 2007).

[40] But by no means are experts required to perform tests under every methodology, even in the context of fire investigations, unless the methodology specifically requires it. *See Hickerson v. Pride Mobility Prods. Corp.*, 470 F.3d 1252, 1257 (8th Cir. 2006) (holding that a fire causation expertôs opinion was admissible where the methodology involved no testing, but rather the application of specialized knowledge to observations of a fire scene).

B. Dr. Elghobashi's Testimony Should Be Admitted

1. Dr. Elghobashi Is Qualified to Testify

Defendants do not take issue with Dr. Elghobashiôs qualifications or impeccable credentials, Plaintiffs will not belabor the issue: Dr. Elghobashi is clearly qualified. Dr. Elghobashi applied factually-relevant conditions to a methodologically sound, validated CFD process to achieve repeatable results.[41] Dr. Elghobashi is at the top of his field, and is eminently qualified to conduct the testing and to render the opinions he offers in this case.[42]

In 2014, Dr. Elghobashi was elected to the prestigious National Academy of Engineering for contributions to understanding and modeling of multiphase turbulent flows.[43] He is currently working with the Department of Defense running complex simulations on a military supercomputer to design an aircraft carrier capable of speeds up to 90 knots. He has worked with the National Institute of Health in using CFD simulation techniques to model the obstruction of the upper airway in pediatric patients.[44] Based on

[41] Ex. 4 (Elghobashi Rep.).
[42] Ex. 24 (Elghobashi CV).
[43] National Academy of Engineers website: https://www.nae.edu/MembersSection/MemberDirectory/107930.aspx. Election to membership in the NAE is among the highest forms of recognition of notable accomplishments in engineering.
[44] Ex. 25, Wang Y, Elghobashi S, *On locating the obstruction in the upper airway via numerical simulation*, RESPIRATORY PHYSIOLOGY & NEUROBIOLOGY. 2014;193:1-10. doi:10.1016/j.resp.2013.12.009.

his CFD model, surgeons had a 100% success rate in the procedure to remove the obstruction.[45]

Indeed, Defendants concede Dr. Elghobashi is qualified and capable of performing CFD.[46]

2. Courts Have Recognized CFD Is A Reliable Method

Defendants do not dispute that CFD is an accepted methodology. Defendantsô experts also recognized the quality of Elghobashiôs work. Indeed, the handwritten notes from some of Defendantsô proffered experts noted Elghobashiôs report was ñpublication qualityò.[47] Defendants have not disputed that Dr. Elghobashiôs opinions will help the jury understand the evidence and decide disputed issues of fact. Dr. Elghobashi and his CFD analysis meet all the requirements of Rule 702 and *Daubert*.

For more than a decade, federal courts have upheld the use of CFD in litigation including the Eighth Circuit Court of Appeals. *See Quiet Technology DC-8 v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333 (11th Cir. 2003); *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209 (Fed. Cir. 2006); *Dejana v. Marine Tech., Inc.*, No, 4:11-cv-1690-JAR, 2013 WL 4768407 (E.D.Mo. Dec. 20, 2013); *Turner v. Liberty Mutual Fire Ins. Co.*, No. 4:07-cv-00163, 2007 WL 2713062 (N.D. OH. Sept. 14, 2007)(allowing testimony based on NIST Fire Dynamics Simulator, a LES-based fire CFD code). The 8th Circuit recognized the reliability of CFD while adopting and applying the holding

[45] *Id.*
[46] Doc. 805 at p. 37.
[47] Ex. 26 (Settles notes) at p. 9.

from *Quiet Tech. See In re Zurn Pex Plumbing Prod. Liab. Litig.*, 644 F.3d 604, 614 (8th Cir. 2011).

3. Defendants' Falsely Accuse Dr. Elghobashi Of Failing To Account For Memarzadeh's Results

Defendants attack Dr. Elghobashiôs methodology in part by alleging that he failed to account for differences between his CFD analysis and that referenced by Memarzadehôs note.[48] That is objectively false and highlights the ñliberties ò Defendants and their counsel have taken in their attacks on Dr. Elghobashi.

Dr. Elghobashiôs report specifically identifies flaws in Memarzadehôs work.[49] In particular, Dr. Elghobashi noted that Memarzadeh used a type of modeling called ñReynolds-averaged Navier Stokesò (RANS).[50] Dr. Elghobashi identified shortcomings with RANS, in particular that RANS is ñincapable of accurately predicting the locations of squames at any time in the OR.ò[51] Dr. Elghobashi concluded ñRANS model cannot compute the instantaneous velocity field needed to accurately calculate the forces on particles, and particle trajectories.ò[52]

Surely Defendants read Dr. Elghobashiôs report and his detailed explanations for the reason why his findings were different (and more accurate) than Memarzadeh.

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[48] 3M has also performed unpublished internal CFD studies in 2015 but have not produced them based on a claim of privilege. Surely if the CFD study performed by 3M was favorable to 3M, that study would have been promptly produced, publicly promoted, and regularly paraded during these MDL proceedings. The silence speaks volumes.
[49] Memarzedah did not publish this work as a peer-reviewed study. It was merely summarized as a letter to the editor.
[50] Ex. 4 (Elghobashi Rep.) at 5.
[51] *Id.*
[52] *Id.*

Defendants asked Dr. Elghobashi essentially nothing about those explanations in deposition. It is objectively false to now claim that Dr. Elghobashi did not distinguish his results from those reported in a prior publication.

Setting aside its pages and pages of bluster, Defendantsô criticisms of Dr. Elghobashi boil down to three *Daubert* issues and one 403 argument. First, Defendantsô claim Dr. Elghobashiôs results are unreliable because he did not validate them. Second, Defendantsô claim Elghobashi used the wrong boundary conditions. And third, Defendants claim that Elghobashiôs results are apparently not the output of a supercomputer simulation, but are instead what they characterize as a mere ñthought experiment.ò Even if these arguments were true ï and they are both false and dishonorably disparaging - none of these arguments would be proper grounds for exclusion.

4. Dr. Elghobashi's Methodology Is Reliable

Defendants also claim (at 40-41) that while CFD in general is reliable, the code that Dr. Elghobashi used has not been validated and therefore required additional testing to be deemed ñreliable.ò Defendants are wrong. Dr. Elghobashiôs code has been validated repeatedly and no additional experiments are legally required.

a) Dr. Elghobashi's CFD Code Has Been Validated

The CFD used for Dr. Elghobashiôs test has been validated. The code, developed by fifteen Stanford University graduate students, has been evaluated every year for the

last fifteen years against a bevy of verification tests.[53] Those evaluations include comparisons to simple flows called ñchannel flows,ò as well as more complicated particle-laden flows, droplet-laden flows, and swirling droplet flows.[54] The code results have been validated to experiments conducted by Pratt & Whitney.[55] Pratt & Whitney designs, tests, and builds turbojet aircraft engines, including high-performance, next-generation, military fighter jet engines for the U.S. Air Force.

In addition, the software code Elghobashi used to complete his CFD model in this case has been validated through a host of peer-reviewed publications.[56] Those confirm the reliability of CFD generally, and of this code specifically, in situations that are far more complex than the one at issue in this case. As Dr. Elghobashi explained, once a CFD code has been validated for a complex situation, it is considered validated for less-complex computation.[57] Here, CFD software that has been regularly used for the complex dynamics of an aircraft engine are more than suitable for use in the less-complex flows of an operating room.[58]

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[53] *See* Ex. 27, Elghobashi Dep. (210:10-211:24).
[54] *Id.*
[55] *Id.*
[56] Ex. 4, (Elghobashi Rep.) p. 11-12. Notably, Defendantsô CFD witness failed to provide any peer reviewed publications establishing that the CFD code he utilized was validated for particle flow. Defendants offer no explanation for why Plaintiffsô expert should be held to a different standard than their own. *See Shuck v. CNH America,* 498 F.3d at 875 (holding that one party should not be heard to complain about a methodology that they themselves used).
[57] Ex. 27, Elghobashi Dep. (210:21-212:20).
[58] Ex. 28, W. L. Oberkampf and T. G. Trucano, *Verification and Validation in Computational Fluid Dynamics*, PROGRESS IN AEROSPACE SCIENCES, vol. 38, pp. 209-272, 2002.

Defendants attempt to confuse the Court with the term validation as it pertains to CFD. Defendantsô refer to NASA and the American Institute of Aeronautics and Astronautics, and correctly quotes the website that ñ[t]he process of determining the degree to which a model is an accurate representation of the real world from the perspective of the intended uses of the model.ò[59] Defendants, however, conspicuously left out the **first sentence** which states that validation pertains to the CFD codes, not for experimental testing of the results. ñThis case discusses Validation Assessment, which focuses on the methods for the ***Validation of a CFD code***[] for simulation of a certain type of flow[].ò[60] This is a process that is used to determine if a CFD code is ñsolving the equations right.ò[61] Once a code is validated for complex systems, as the code used by Dr. Elghobashi has been, the CFD results are considered reliable for less complex systems and need not be revalidated. Contrary to Defendantsô disingenuous attempt to confuse the issue, the code used by Dr. Elghobashi is validated.

b) Dr. Elghobashi's CFD Does Not Require Additional Testing

CFD does not require a follow-up experiment. One of the reasons CFD and other forms of computer simulation have achieved widespread acceptance is that they enable analysis and visualization of situations that are not readily amenable to real-world

[59] Def. Mot. at 41.
[60] NPARC Alliance CFD Verification and Validation Web Site, https://www.grc.nasa.gov/www/wind/valid/tutorial/valassess.html (last visited September 30, 2017).
[61] *Id.*

experimentation. CFD is a mature technology, having been used for over three decades to model some of the most complex airflows in the world (and beyond).[62]

Defendants cite no law that requires physical testing to confirm the results reached by CFD. Unlike Defendantsô own CFD analysis, Dr. Elghobashiôs CFD analysis is testable. Contrary to the report provided by 3Môs expert Abraham, Dr. Elghobashiôs report provides all the information (geometry, initial conditions, equations, boundary conditions, etc.) so that his results can be replicated and tested. Not one of those CFD cases cited above even hints obliquely at any requirement to conduct a follow up experiment validating the results. There is no such requirement. The Seventh Circuit soundly rejected the same argument 3M attempts to peddle here. *See Lapsley*, 689 F.3d at 815-816. There, the defendant argued that an expert should have done physical tests to validate the results of computer simulation. *Id.* The Seventh Circuit disagreed, holding:

> [Defendantôs] argument also overlooks the fact that simulation is one of the most common of scientific and engineering tools. Around the world, computers simulate nuclear explosions, quantum mechanical interactions, atmospheric weather patterns, and innumerable other systems that are difficult or impossible to observe directly. A mathematical or computer model is a perfectly acceptable form of test.
>
> We do not require experts to drop a proverbial apple each time they wish to use Newtonôs gravitational constant in an equation. Similarly here, the burden of proof at trial, and certainly the guideposts of reliability attached to the *Daubert* inquiry, did not require [plaintiffôs expert] to try to recreate

[62] NASA regularly uses CFD to simulate, for example, heating rates on the Mars lander during descent through the Martian atmosphere. *See, e.g.*, https://ntrs.nasa.gov/search.jsp?R=20040001189.

> the binding up of a ten thousand pound spring to produce a potentially deadly jet of industrial grease. [Defendant] was free to raise the lack of physical tests of the accident with the jury, and to attack any aspect of the mathematical model that was used in place of physical re-creations.

Lapsley, 689 F.3d at 815-816. Like the expert in *Lapsley*, Dr. Elghobashi used a validated, reliable, repeatable methodology to produce his simulation results. There is simply no legal requirement for physical testing.

5. Dr. Elghobashi's Boundary Conditions Are Not Grounds For Exclusion

Dr. Elghobashi used appropriate inputs. Defendantsô disagreement with those inputs is not grounds for exclusion. Precedent dictates that disputes about inputs go to weight, not to admissibility. The Eighth Circuit has repeatedly applied that principle, including through its adoption of the holding from *Quiet Tech.* in *In re Zurn,* 644 F.3d at 614. Courts have consistently held that the purported use of potentially wrong inputs ñgo to the weight, not the admissibility, of the evidenceé .ò *Quiet Tech*, 326 F.3d at 1345-46.

Defendants (at 55) quote *Bonner v. ISP Techs., Inc*., 259 F.3d 924, for the proposition that ñtestimony must é be excluded if it is óso fundamentally unsupported that it can offer no assistance to the jury,ôò but Defendants omit the outcome of that case. The Eighth Circuit held that both of plaintiffôs expertsô opinions were based on sufficiently reliable methodologies to be admitted. *Bonner*, 259 F.3d at 930-32 (emphasis added). Nor does Defendantsô citation of *In re Zurn* help their case: there, too, the Eighth Circuit admitted expert opinions despite a disagreement about the expertôs factual assumptions. 644 F.3d at 614.

In re Zurn is particularly relevant because it involved a dispute about the propriety of the expertôs ñinputs.ò *Id*. at 615-16. Among other things, the defendant criticized plaintiffsô expert for ñassumingò one of the inputs, rather than gathering that input from available data. *Id*. at 615. The Eighth Circuit held that a mere dispute over inputs was not enough to require exclusion. *Id*. The court accepted the expertôs ñreasonable assumptionò based on Zurnôs own data where the expert lacked other more direct data. *Id*. at 615-616.

The narrow exception where inputs may be excluded by the court is where an expert uses data that is indisputably wrong. But that does not apply to Dr. Elghobashiôs work. Dr. Elghobashi used the best data available to him. As he testified, he lacked the resources to directly measure the temperature of air leaving the drape.[63]

But unlike *In re Zurn*, Dr. Elghobashi did not resort to merely ñassumingò the air temperature. Dr. Elghobashi observed Defendantsô documents and video in which Defendants characterized the air temperature.[64] Dr. Elghobashiôs inputs, therefore, come directly from Defendants.[65]

To the extent Defendants contest Dr. Elghobashiôs use of those or any other inputs, Defendants are free to cross examine him at trial. *Daubert*, 509 U.S. at 596. ñAn

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[63] Ex. 27, Elghobashi Dep.(207:18-208:13).
[64] Ex. 29 (3MBH00042553)(522 Temp Tests by 3M); Ex. 4 (Elghobashi Rep.) 31-32.
[65] Defendants reference a temperature observed by Plaintiffsô expert Dr. Yadin David to indicate that Expert Elghobashiôs boundary condition is contradicted by other Plaintiffsô experts. Only by omitting the context of Dr. Davidôs measurement can 3M create a contradiction. In his report, Dr. David specifically stated that he ñfound that this used exemplar unit did not appear to be performing normallyò and that ñthe exemplar device was in need of servicing.ò Ex. 30 (David Rep.) p. 15. In addition, the used exemplar device (purchased used via eBay) contained numerous fault codes. *Id.* At 10.

expertôs opinions are not inadmissible simply because an underlying assumption may be contestable.ò *Marvin Lumber v. PPG Indus.*, 401 F.3d 901, 916 (8th Cir. 2005). Dr. Elghobashiôs selection of temperature inputs does not render Dr. Elghobashiôs analysis inadmissible.

6. Dr. Elghobashi's CFD Is No Mere "Thought Experiment"

Defendants (at 56) twist Dr. Elghobashiôs testimony to support their claim that Elghobashiôs CFD simulation is a mere ñthought experiment.ò Dr. Elghobashi testified that he relied on Defendants documents and videos to establish his boundary conditions.[66] Dr. Elghobashi further testified that he thought hard about the nature of the analysis and the inputs before he created the CFD.[67] Contrary to Defendants rendition of the facts (at 39), however, Dr. Elghobashi calculated the exit temperature of the air at the end of the drape. Dr. Elghobashi stated the following:[68]

> A. We discussed this today at length. All the air flow that leave the Bair Hugger has to leave the drape somewhere. So we distribute uniformly on that drape edge.
> Q. And is that -- is that the calculations when you talked about, you thought about it a lot, that's -- that's the boundary connection?
> A. That's regarding the temperature. But the -- the -- regarding the mass loads, it's conserve. Means on a flow -- the air mass flow rate that leave the blower has to come out along the drape because the drape covers everything. That's no assumption.
> Q. Okay.

[66] Ex. 27, Elghobashi Dep. (66:16-68:22).
[67] Ex. 27, Elghobashi Dep. (114-117).
[68] Ex. 27, Elghobashi Dep.(247:19-249:16); *See also* Ex. 31, Ex. 15 of Abraham Depo.

A. The assumption is in the temperature of the edge of the drape.
Q. Okay. Number three, we've already talked about the surgical lamp.
A. Because that was a typo.
Q. Okay.
Oh, by the way, what are your assumptions based upon?
MS. ANDREWS: Do you need this (indicating)?
MR. ASSAAD: I don't need it.
BY MR. ASSAAD:
Q. What are your assumptions based -- you just -- I mean, you base your assumptions on something, correct?
A. About which one? Flow rate or --
Q. About -- about the temperature.
A. The temperature, yeah, I did some estimate calculation, yes.
Q. Okay. You did calculations?
A. Not a computer; hand calculations.
Q. And they're mathematical calculations?
A. Correct.
Q. And that -- those calculations were based on your education, training and experience?
A. Yes.
MR. GORDON: Object to the form of question.
BY MR. ASSAAD:
Q. And going back to the calculation that you did, you actually saw a setup that was in Santa Monica in September which a registered nurse prepared --
A. Correct.

Dr. Elghobashi calculated the temperature used in his CFD model.[69] It was not made up; it was based on mathematical calculations.[70]

[69] Ex. 27, Elghobashi Dep.(247:19-249:16).
[70] *Id*.

Although Defendantsô expert Abraham believes the calculations to be incorrect, such is not grounds to exclude Dr. Elghobashiôs as an expert. *See In re Zurn*, 644 F.3d at 615-16. Additionally, Defendantsô other proffered engineering expert, Dr. Kuehn, concluded Dr. Elghobashi did the calculations correctly.[71]

Defendants take that statement out of context and imply that Dr. Elghobashi performed some kind of free-form mental exercise instead of a mathematical calculation. And, of course, Defendants know that Dr. Elghobashiôs analysis was no mere ñthough experiment.ò Dr. Elghobashi testified repeatedly that he thought hard about this project to make sure he had the right boundary conditions, used the right analytical techniques and performed hand calculations.[72] He carefully considered the physics of the problem.[73] He considered whether ñDirchiletò or ñNeumannò rules applied.[74]

Dr. Elghobashi applied the same methodology he uses when he is performing simulations for publication and in support of government research.[75] 3M has identified no basis to support its contention that his opinion is a mere though experiment.

7. Dr. Elghobashi's Testimony Should Not Be Excluded Under Rule 403

Defendants argument for exclusion under Rule 403 is essentially that Dr. Elghobashiôs credentials are so good that the jury may have a hard time not believing him. Defendants offers zero analysis to support its request.

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[71] Ex. 5 Kuehn Dep. (260:3-12).
[72] Ex. 4, Elghobashi Report
[73] *Id.*
[74] *Id.*
[75] Ex. 24 (Elghobashi CV); *see also* Ex.27, Elghobashi Dep. (220:12-20).

None of the cases cited by Defendants supports their requested relief. In *United States v. Blade*, a defendantôs expert was excluded because his ñabstract, generalò testimony about the process of eyewitness identification was of little or no value to the juryð the expert had not had any contact with the witnesses or with the defendants, but was merely providing a general overview of the issues associated with eyewitness identifications. 811 F.2d 461 at 464-65 (8th Cir. 1987).

As described *supra*, at 19-20, *Werth's* experts were excluded on *Daubert* grounds. Having determined that the experts failed to follow NFPA 921ôs methodology, the court also held that it would exclude the testimony on the grounds that it had little to no probative value and was unfairly prejudicial because a jury might find for the plaintiff, a baby who was badly burned just days after being born. 856 F. Supp. 2d at 1067.

The remedy Defendants seek here is available only where an expertôs testimony is not very probative *and* its value is ñsubstantially outweighed by the danger of unfair prejudice.ò *See Daubert*, 509 U.S. at 595. Defendants have not shown that Dr. Elghobashiôs opinions lack probative value or that they would unfairly prejudice the jury.

Dr. Elghobashiôs opinions are highly probative because they demonstrate the mechanism by which Bair Hugger exponentially increases the number of 10µm particles over the surgical site.[76] On the one hand that fact should not be reasonably in disputeð 3M has testified that all studies show Bair Hugger increases particles in the air over the

[76] Ex. 4 (Elghobashi Report).

surgical site, including studies 3M has funded.[77] But Dr. Elghobashiôs study is especially probative because he analyzed 10µm particles. That represents the average size of a skin squameð a particle upon which CFUs can hitch a ride into the surgical site. Everyone in this case agree that at least 10µm sized particles can carry CFUs.[78]

Just a single CFU can cause a deep joint infection.[79] Defendantsô Infectious Disease expert testified that up to 40% of the particles in an OR carry bacteria.[80] Peer-reviewed publications have identified a direct correlation between 10 micron particles and increased numbers of CFUs.[81] Defendants criticize Stocks et. al.ôs conclusion[82] in the briefs (though barely addressed it in their expert reports). In deposition, Defendantsô own expert agreed with Stocksô conclusion.[83]

Dr. Elghobashiôs CFD simulation of 10µm particle flow is an important ñbrickò in the evidentiary wall that otherwise includes evidence that CFUs cause deep joint infections, CFUs can move through the air on 10µm particles, and Bair Hugger increases the number of particles over the surgical site.

The *Daubert* framework is intended to address the risk that a jury will be improperly swayed by scientific evidence presented by a well-credentialed witness. Dr. Elghobashi has unquestionably impressive credentials. He is a world-class expert in

[77] Ex. 2, 30(b)(6) Depo. (258).
[78] *See* Defs Mot. at 36, fn. 148.
[79] Ex. 32, Jarvis Dep. (109:24-110:21).
[80] Ex. 1, Wenzel Dep. (50:2-15).
[81] Ex. 19 (Stocks) at 202.
[82] Ex. 19.
[83] Ex. 1, Wenzel Dep. (309:19-310:3; 322:18-21).

computational fluid dynamics and particle flow simulation. But his impeccable credentials should not count *against* Plaintiffs or against him in the absence of evidentiary deficiencies. Dr. Elghobashi applied an accepted methodologyð the same one his uses in academia, publications, and non-litigation research. He used the best data and tools available to him under the circumstances. Dr. Elghobashiõs testimony and opinions are relevant, reliable, and should be admitted by this Court.

C. Dr. David's Opinions Should Be Admitted

As with other engineering experts, Defendants take issue with a few narrow opinions included in Dr. Davidõs report, but asks the Court to exclude *all* of Dr. Davidõs opinions. Defendantsô request is overbroad, and should be denied. Plaintiffs have provided a detailed discussion of Dr. Davidõs expertise in its response to Defendantsô separate motion.[84]

Dr. Yadin David is a world class biomedical engineer and risk manager who has spent his career evaluating medical devices and adverse events, consulting for medical device companies on the creation of new products, and advising employees of the U.S. Food & Drug Administration (FDA).[85] The bulk of 3Mõs attacks on Dr. Davidõs opinions concern his qualifications, but 3Mõs Motion badly misrepresents and underappreciates the nature of Dr. Davidõs credentials and background. 3Mõs remaining complaints purport to attacks Dr. Davidõs methodology, but these complaints distort the record and ignore Dr. Davidõs testimony.

[84] Doc. 866.
[85] Ex. 33 (Yadin CV).

1. Dr. David is qualified to assess medical devices for clinical risk.

Courts have determined ñDr. David is an eminently qualified biomedical engineer.ò *See McLane v. Ethicon Endo–Surgery, Inc*., 2014 WL 12621192, at *2 (M.D.Fla.2014). He is the Chairman of the Clinical Engineering Division of the International Federation of Medical and Biological Engineering (IFMBE), and has been awarded the Lifetime Achievement Award from the American College of Clinical Engineering (ACCE).[86] Dr. David also served as an advisor to the World Health Organization (WHO) on Health Infrastructure and Technology.[87] Dr. David also sits on the Editorial Board of the Journal of Health and Technology.[88] As Dr. David explained: ñI've been working in the biomedical devices field for four decades and use my expertise to understand how a device works safely and what risk is associated with them, seeing it from the clinical side.ò[89]

3Môs first attack on Dr. David is that he is ñunqualified to opine about risk in the clinical setting.ò (Doc. 805, p. 60). 3M wrongly claims that ñDr. Davidôs biomedical engineering experience does not qualify him to opine on issues of medical causation.ò[90] In support of this argument, 3M cites *Barrett v. Rhodia, Inc*., 606 F.3d 975, 982 (8th Cir.2010), but *Barrett* involved a safety engineer with expertise in industrial plant safety procedures rather than medical issues. 3M fails to cite any authority excluding such

[86] Ex. 30(David Rpt. 3); Ex. 33 (David CV) 3.
[87] Ex. 33(David CV) 3.
[88] *Id*. at 2.
[89] Ex. 34, David Dep. (65:20 to 65:25).
[90] Doc. 805, p. 61

testimony from a biomedical engineer, who would routinely be considering issues regarding medical issues and causation as a part of their professional responsibilities.

Biomedical engineering ñincludes how a device should be designed and constructed, as well as the proper design and implementation of studies to determine the existence, nature and magnitude of potential risks and benefits associated with various device designs and the extent to which those risks and benefits are realized in clinical practice.ò *Taylor v. Danek Medical, Inc*., 1999 WL 310647, at *4 (E.D.Pa.1999). This is exactly what Dr. David set out to do in his report, as he described in deposition:

> In my work, Iôm expected to read clinical literature and scientific publications. I am educated, trained, and have the experience to understand the study structure and the strength of the conclusions. And in my evaluation of various medical devices, at the hospital I worked for over 25, 30 years, part of the process was to review current medical and scientific literature relating to device performance é that looked at overall what you asked earlier, benefit-to-risk ratios and understand what the product risk based on the information from the manufacturers, but also based on experience that comes from clinical studies that published in peer-reviewed journals.[91]

Just as in prior cases, Dr. David has directly applied his decades of ñexperience in the risk-assessment of healthcare equipment.ò *Woodard*, 2012 WL 3475079 at *8. Understanding and applying clinical information and assessing clinical risk is a fundamental component of biomedical engineering. *See, e.g., In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 711 F.Supp.2d 1348, 1373 (M.D.Ga.2010) (Admitting biomedical engineering testimony as to ñhow the design and

[91] Ex. 34, David Dep. (280:15 to 281:9).

construction of [the product] can cause the complications.ò). Indeed, FDA regulations recognize that biomedical engineers are qualified to assess the clinical risk of a medical device in adverse event investigations. Under the FDAôs medical device adverse event reporting statute, manufacturers must report events that ñmay have caused or contributed to a death or serious injury.ò *See* 21 CFR 803.20. However, manufacturers are not required to report an event if the facts would ñlead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury.ò *Id.* Under the statute, ñ[p]ersons qualified to make a medical judgment includeé biomedical engineers.ò *Id.*

Moreover, Dr. David possesses far more relevant expertise than the typical biomedical engineer because he has extensive direct experience in the evaluation of medical devices for patient risk. For almost twenty years, Dr. David served as Director of Biomedical Engineering at the Texas Medical Center, where he oversaw medical devices for three hospital facilities ï Texas Childrenôs Hospital, St. Lukeôs Episcopal Hospital, and the Texas Heart Institute.[92] Dr. David was the creator of the groundbreaking ñMedical Technology Evaluation Committeeò at the Texas Medical Center, and he served as its director from 1989 to 2008.[93] As Dr. David explained:

> As part of my work in this capacity and other evaluative functions, I have examined products to support and facilitate the evaluation and deployment decisions of various types of medical technology. The selection process typically involved

[92] Ex. 33 (David CV) at 3.
[93] Ex. 30 (David Report) at 7; Ex. 34, David Dep.(280:15-281:9); Ex. 33 (David CV) at 7.

> reviewing the product, understanding the environment of use and potential risks, researching the regulatory background, and considering the evidence gathered and the conclusions reached in peer-reviewed scientific publications.[94]

In the *Ethicon* litigation, the U.S. District Court for the Middle District of Florida discussed Dr. Davidôs extensive qualifications in risk management and adverse event investigations:

> The Court takes note of Dr. Davidôs experience in the selection process and servicing of health equipment; training of hospital staff in the safe use of medical equipment; his varied roles in developing and leading professional organizations; his extensive educational background; and over one hundred publications within the intersection of medicine and engineering, including those on risk management and adverse event investigations of medical products.

McLane v. Ethicon Endo–Surgery, Inc., 2014 WL 12621192, at *4 (M.D.Fla.2014). Similarly, in the District of Wyoming, the court found Dr. David qualified to opine on the risk of a medical device, and admitted his opinion that ñStryker manufactured and marketed a device that was unsafe and presented unreasonable biomedical engineering risk in connection with its use in intra articular space.ò *Woodard*, 2012 WL 3475079 at *9. The court in *Woodard* also admitted Dr. Davidôs opinion that Stryker ñfailed to warn potential end users about the risks resulting from use of this device.ò *Id.* Dr. David is likewise qualified to render similar opinions in this case.

[94] Ex. 30 (David Report) at 4.

2. Dr. David possesses extensive experience in managing and studying patient warming devices.

3Môs next complaint is that Dr. David had ñno meaningful experience with the Bair Hugger system.ò[95] According to 3M, experts should not be allowed to testify about the device unless they have prior special knowledge about the Bair Hugger. However, the fact that Dr. David has never worked specifically with the Bair Hugger does not disqualify him as an expert. Rather it is fully consistent with methodology outside of litigation. For decades, Dr. Davidôs job was to make himself familiar with the design, mechanical function, and potential patient risk of new medical devices, including and most especially devices with which he had no previous experience.

Moreover, Dr. Davidôs experience in the field of patient warming is vast. At the Texas Medical Center, Dr. David has directly overseen hospital practices with regard to patient warming.[96] In addition, ñfor over 30 years [he] was involved in reviewing warming devices for adult and pediatric patients.ò[97] These devices included the full array of warming modalities, whether ña literally oven-warmed blanket or devices that use fluids to warm patients or cool them or radiation-based devices that they are used in different environments.ò[98] In particular, Dr. David ñbecame intimately familiar with the issue of maintaining or warming patients under trauma situations.ò[99] Dr. David also

[95] Doc. 805, p. 61
[96] Ex. 34, David Dep. (202:19-23).
[97] *Id.* at (203:6 to 203:10).
[98] *Id.* at (203:10 to 203:14).
[99] *Id.* at (204:7 to 204:9).

performed several studies and published multiple research papers on pediatric ñforced warm airò devices known as Isolettes.[100]

In addition, Dr. David published multiple studies on patient warming devices and clinical outcomes in cardiovascular surgeries at St Lukeôs Episcopal Hospital, home of the Texas Heart Institute, including study of heater-cooler devices.[101] Dr. David was part of the team that investigated and determined a new cleaning protocol for heater-cooler units.[102] Dr. David also has experience in studying the influence of air exchanges in the surgical theater, as well as experience reviewing and evaluating operating room pollution from anesthesia-based gases.[103] In short, Dr. David is eminently familiar with patient warming modalities as well as ñthe proper design and implementation of studies to determine the existence, nature and magnitude of potential risks and benefits associated with various device designs and the extent to which those risks and benefits are realized in clinical practice.ò *Taylor*, 1999 WL 310647 at *4.

3. Dr. David familiarized himself with the relevant body of science, including articles frequently touted by 3M.

3M next attacks Dr. Davidôs methodology, wrongly claiming that his literature review was ñindiscriminate,ò and that he did not review any ñarticles finding no increase in bacteria during use of the Bair Hugger system.ò[104] 3M argues that there are a number of published studies which are favorable to the Bair Hugger, and that Dr. Davidôs

[100] *Id.* at (204:10-205:7).
[101] *Id.* at (209:10 ï 210:23).
[102] *Id.* at (216:12-217:5).
[103] *Id.* at (213:24-214:5).
[104] Doc. 805, p. 62.

analysis does not address any of these articles. This is simply false. Dr. Davidôs report includes a discussion of articles frequently cited by 3M in support of the Bair Hugger. He also cited these studies in deposition.[105] In addition, Dr. David discussed how his materials included a ñreview article of existing literature by Wood, Moss and Keenan.ò[106] This article from The Journal of Hospital Infection collected and analyzed the recognized body of published literature on the issue of forced air warming contamination, including the studies touted by 3M. Dr. David noted in his report that given the risk identified from Bair Hugger use, ñthe authors recommended that facilities consider the use of alternative warming technologies.ò[107] Dr. David also reviewed the reports of Plaintiffôs other clinical experts.[108] Finally, in addition to the deposition of company executives, clinical staff, and engineers, Dr. David has reviewed the testimony of 3Môs retained clinical consultant.[109] All of the contested studies have been discussed at length in these depositions.

In any case, these disputes about which studies the experts found important are matters for cross examination. ñAs a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility.ò *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir.1995). This is not a situation where an expert abjectly failed to familiarize himself with the relevant body of literature on the

[105] *See, e.g.,* Ex. 34, David Dep. (304:23 to 305:12).
[106] Ex. 34, David Dep. (273:10 to 273:11). *See Ex. 35,* Wood, Moss, Keenan, Reed, and Leaper, *Infection control hazards associated with the use of forced air warming in operating theatres*, JOURNAL OF HOSPITAL INFECTION (2014).
[107] Ex. 30 (David Rpt.) at 31.
[108] *Id.* at 47.
[109] *Id.* at 46.

subject of his opinion, as was the case with 3Môs expert Jim Ho. Here, Dr. David performed a literature review consistent with and even more thorough than he would normally conduct when performing a medical device risk analysis outside litigation.

4. Dr. David considered the documented efficiency of the Bair Hugger filter and supported his opinions with relevant industry materials.

3Môs attacks on Dr. Davidôs opinions regarding the Bair Hugger filter are misleading. For example, 3M claims that ñDr. David has not seen any of the test reports confirming that Bair Hugger filters meet the MERV 14 efficiency standard.ò[110] In deposition, Dr. David gave the opposite testimony:

> Q. Have you seen indication that the filter for the model 750 Bair Hugger device meets MERV 14 standards?
>
> A. There is test results within the documents that I have here of testing that filter efficiency.[111]

The efficiency of the Bair Hugger 750 filter has been extensively discussed in company documents, employee depositions, and in the published literature, all of which Dr. David reviewed.[112] Moreover, Dr. David disputes 3Môs contention that MERV 14 is sufficient ñfor operating room air handlers.ò[113] As Dr. David testified, the ASHRAE standards relied upon by 3M recommend MERV 14 for general surgery purposes, but

[110] Doc. 805, p. 63.
[111] Ex. 34, David Dep.(234:25- 235:6).
[112] *See generally* Ex. 30 (David Rep.).
[113] Doc. 805, p. 63.

recommend HEPA filters for protective effect environments.[114] Dr. David explained that ASHRAE Standard 62.1 and other industry guides all ñare saying that we have to have filters with HEPA efficiency in those protective environments where the threat of infection in orthopedic surgery is higher than in other locations.ò[115] In addition to ASHRAE Standard 62.1, Dr. David also testified about his review of hospital policies, such as the operating room ventilation standards in place at the Texas Medical Center, which require MERV 18 HEPA filters in orthopedic surgical suites.[116]

> Orthopedic Operating Room Suites designed for surgery or bone marrow transplants shall have an outside ventilation rate of 4 air changes per hour and a recirculation rate of 40 air changes per hour. The orthopedic OR Suite shall be maintained at the required minimum positive pressure with respect to the corridor and adjacent rooms or spaces per AIA requirements. Filter supply air to Orthopedic OR Suites using MERV 18 HEPA Filters.

As Dr. David explained, this ventilation standard ñis an institutional policy relating to how standards should apply to the construction of personal protective environment in similar spaces and using the standard that ASHRAE has structured.ò[117] In addition, Dr. David relied on a publication from Camfil, the filter technology company that performed filter testing on the Model 750 filter. Camfil also publishes an industry guide concerning filters in health care settings. As Dr. David noted, this guide contains a

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[114] Ex. 36, ASHRAE Minimum Filter Efficiencies, Addendum r to ANSI/ASHRAE/ASHE Standard 170-2008, *Ventilation of Health Care Facilities.*
[115] Ex. 34, David Dep. (262:8 to 262:12).
[116] Ex. 37, Texas Medical Center, Patient Treatment Air Handling Distribution Standard, D304101, p. 3
[117] Ex. 34, David Dep. (154:14 to 154:19).

ñrating and filter designation based on the ASHRAE standard as well.ò[118] The recommendations likewise make a distinction between general purpose and high-risk operating rooms, as shown below:[119]

Filter Efficiencies for Central Ventilation and Air Conditioning Systems in General Hospitals

Minimum Number of Filter Beds	Area Designation	Filter Bed #1 Filter Efficiency	Filter Bed #2 Filter Efficiency
2	Orthopedic operating room Bone marrow transplant operating room Organ transplant operating room	MERV 8 MERV-A 8	HEPA filters at air outlets
2	General procedure operating rooms Delivery rooms Nurseries Intensive care units Patient care rooms Treatment rooms Diagnostic and related areas	MERV 8 MERV-A 8	MERV 14 MERV-A 14
1	Laboratories Sterile storage	MERV 13 MERV-A 13	

Finally, 3M repeats its criticism that Dr. David has not personally examined the original filter used in the Model 500 series, the predecessor to the Model 750. This argument is disingenuous. Having reviewed performance documentation and extensive testimony regarding both filters, Dr. Davidôs report describes the difference in efficiency between the original Model 500 series high-efficiency filter and the Model 700 series lowered-efficiency filter. Moreover, his report discusses the fact that the original Model

[118] *Id.* at (154:20-22).
[119] Ex. 38, Camfil Clean Air Solutions Guidelines, p. 10

500 series high-efficiency filter has not been manufactured for nearly ten years. [redacted] Therefore, he examined a Model 750 filter, but it was impossible for Dr. David to examine the original 500 series filter personally. Even if the original 500 series filter had been available, choosing not to examine it personally is a matter for cross-examination, not *Daubert*.

D. Koenigshofer's Opinions Should Be Admitted

Defendants raise a litany of complaints about Dan Koenigshoferôs opinions in the factual background section of their memorandum, but limit their formal motion to exclusion to just four criticisms. First, Defendants claim Koenigshofer is not qualified. Second, they claim Koenigshofer made things up. Third, they criticize his use of common sense. Fourth, Defendants identify a shortcoming in Koenigsoferôs calculation of the CFUs per hour to which a patient would be exposed. Finally, Defendants argues that Koenigshofer should have considered Defendantsô litigation-derived testing of filter efficiency. While Defendantsô motion asks the court to exclude all of Mr. Koenigshoferôs opinions, they have briefed only a few narrow opinions. Defendants therefore concede the remainder of Koenigshoferôs testimony is admissible.

1. Koenigshofer is qualified to offer the disclosed testimony

Contrary to Defendantsô argument (at 53), Koenigshofer is qualified. Rule 702 requires that an expert be qualified by ñknowledge, skill, experience, training, or

education. The Eighth Circuit has held that an expert may qualify as an expert where he possesses sufficient knowledge obtained from practical experience. *See Fox v. Dannenberg*, 906 F.2d 1253, 1256 (8th Cir. 1990).

Mr. Koenigsoferôs professional experience outside of litigation includes more than 35 years of engineering and project management experience focused on health care facility HVAC systems.[120] He was a principle author on the ASHRAE manual setting forth best practices for hospital HVAC systems.[121] His specific expertise includes maintaining positive pressure in OR. He has extensive experience on the HVAC system which supplies air to OR.[122] He has experience with the dual filtration system used to supply clean air to the OR and maintenance thereof.[123] He has worked on the air mixing rate between recycled air and fresh air in OR.[124] He is an expert in the air pressure drop downstream from a filter. He is on the same ASHRAE committee as defendantsô expert Mr. Keen (whom Defendants assert is an expert).[125] But unlike Mr. Keen, Mr. Koenigshofer consults with hospitals on setup and testing of OR HVAC systems.[126]

Apart from his applied experience, Mr. Koenigshofer has published in the relevant field. Defendantsô own motion quotes in part a paper he published well before he became involved in this litigation. Koenigshoferôs paper focused on OR airflows and the impact

[120] Ex. 39, Koenigshofer Report
[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] *Id.*
[125] *Id.*
[126] *Id.*

of the HVAC system on surgical site infections. It is essentially the precise issue for which Defendants now claim Koenigsofer lacks qualifications. That is just one of the many papers he has written on hospital and OR HVAC systems and aspects thereof.

How defendants can now argue that Koenigshofer is not qualified to testify about those subjects is a mystery.

2. Defendants Takes Koenigshofer's Testimony Out of Context

It is disingenuous for Defendants to claim (at 53) that Koenigshofer ñmade things up.ò In so argument, they have taken Koenigshoferôs words wholly out of context. When understood in the context of the questioning, Koenigshoferôs testimony highlights the reasons why Defendantsô internal filtration efficiency tests are not reliable.

Koenigshoferôs concerns about proper filter seating and gaskets in Defendantsô tests are informed by his experience as the editor-in-chief of the HVAC design guide for hospitals and clinics and his work on the ASHRAE 170 design committee.[127] Koenigshofer appropriately pointed out that Defendantsô filters were tested in an artificial environment, not in the Bair Hugger assembly.[128] That is important because the filter seating and gaskets are an important part of a filter assembly. This is ñcommon sense.ò[129] If particulates in air can go around a filter, then the filter will not capture those particulates.

[127] Ex. 39, Koenigshofer Report.
[128] Ex. 40, Dan Koenigshofer Dep.(292).
[129] Ex. 40, Dan Koenigshofer Dep. (187:1-11).

To put a finer point on that argument, Koenigshofer postulated that the filters were installed in a laboratory mock-up with ñwonderful perfect gaskets installed by a Ph.D technician in the laboratory.ò[130] Admittedly, Koenigshofer did not know who installed the filters because Defendantsô testing results do not supply any of the details of the protocol.[131] His whole point was that the study did not replicate real-world usage (and for that reason need not be considered).

At the end of the day, Defendantsô complaints about Koenigshofer ñmaking things upò is not a valid ground to exclude any testimony.

3. Koenigshofer's Use of "Common Sense" is Appropriate

At some point, all experts rely on common understanding without specific citations. Engineers provide citations for those aspects of their reports that are novel or perhaps not straightforward. But just as an engineer need not explain an opinion all the way back to first principles, an expert like Koenigshofer should not be required to provide detailed bases for undisputed facts.

Specifically, Defendants complain (at 54) that Koenigshofer did not provide a specific basis for concluding that particles counts are an appropriate surrogate for airborne bioburden. As described elsewhere in this brief and in Plaintiffs Response Opposing Defendants Summary Judgment Motion, there is no reasonable dispute about this issue. Defendantsô own expert testified that 40% of OR particles contain bacteria.[132]

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[130] Ex. 40, Dan Koenigshofer Dep. (291-2).
[131] Ex. 40, Dan Koenigshofer Dep. (340).
[132] Ex. 1, Wenzel Dep. (50:2-15).

Defense expert Dr. Kuehn likewise agreed that particle counting can be appropriately used to measure the total (bacterial) aerosol concentration in an operating room (within the range of the instrument).[133] Kuehn also agrees particle testing provides real-time data where biological sampling is delayed while the samples are sent for culturing.[134]

Peer-reviewed literature found a direct correlation between airborne particles and increased numbers of CFUs.[135] Defendants have offered no reasons to backtrack from their expertôs concession or the results of the peer reviewed publication.

Moreover, Koenigshoferôs testimony is based on his 35 years of practical experience.[136] Hospitals do not filter OR air to merely remove irrelevant particles. They filter the air to remove bacteria that could cause infections. If there were no association between bacteria and particles, hospitals would not go to such great lengths to filter particles.

4. Koenigshofer's Calculations

During his deposition[137], Koenigshofer determined that his report contained a mathematical error in calculating the CFUs per hour to which a patient would be exposed. Given that error, Plaintiffs will withdraw the portion of his testimony that calculates the number of CFUôs per hour that a Bair Hugger and its associated blanket would emit. In particular, Plaintiffs withdraw the calculations and opinions disclosed on

[133] Ex. 5, Keuhn Dep. (294:2-5).
[134] *Id*. (90:19-91:9).
[135] Ex. 19, Stocks Article
[136] Ex. 39, Koenigshofer Report
[137] Ex. 40, Koenigshofer Dep.

pages 21-22 of Koenigshoferôs report, as well as the summary of that opinion at the conclusion of his report.

5. Koenigshofer was Right to Ignore Defendants' Filter Tests

Defendantsô wrongly argue (at 54) that ñKoenigshoferôs criticism of the Bair Hugger intake filersò should be excluded because he proceeded ñwithout having reviewed any of the test reports showing that they meet the same efficiency standard as the operating room filters.ò Defendantsô internal testing, conducted unilaterally during the course of this litigation, is unreliable and did not need to be considered by Koenigsofer in rendering his opinions. Defendants are not criticizing Koenigsofer for ignoring publications or peer-reviewed studies. Defendantsô only evidence that their filters meet MERV-14 standards are their own tests, conducted during the course of litigation.[138] Koenigshofer identified shortcomings in 2016 filter testing proffered by Defendants that justify his refusal to consider the tests.[139] Moreover, as described above, those tests are inconsistent with results achieved by unrelated third parties.[140]

E. Buck's Testing Should Be Admitted

Defendantsô entire basis for excluding Mr. Michael Buckôs testimony[141] is one conclusory paragraph.[142] While Defendants request exclusion under *Daubert*, Defendants

[138] Def. Mot. at 27, fn. 105.
[139] Ex. 40, Koenigshofer Dep.
[140] Ex. 41, Reed M, Kimberger O, McGovern PD, Albrecht MC, *Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions*, AANA JOURNAL (2013 Aug);81(4):275-80.
[141] Ex. 42, Buck Dep.
[142] Def. Mot. at 54.

offer no criticism of Mr. Buckôs qualifications to perform the testing he performed, no explanation for how his methodology is unreliable or whether his technique is generally accepted.

Defendantsô entire argument is that Buck counted particles and not bacteria.[143] But that alone is not sufficient to exclude his testimony, either under *Daubert*, Rule 401, or Rule 402. Defendantsô assumptions about the relevance of Buckôs testing is simply wrong.

Evidence is relevant if it ñhas any tendency to make a fact more . . . probable than it would be without the evidenceò and ñthe fact is of consequenceò to the case. F.R.E. 401. It is not necessary that each piece of evidence prove the ultimate fact in the case. The comments to Rule 401 note, ñit is not to be supposed that every witness can make a home run.ò (internal citations omitted).

Michael Buck counted and characterized the size of particles emitted by Defendantsô Bair Hugger.[144] He found particles ranging from sub-micron to particles greater than 10µm.[145] 3M focuses on the large number of ñirrelevantò particlesð too small to carry bacteria.[146] But the converse is ignoredð Buck detected particles that were larger than 10µm.[147] That is important because, as Defendantsô brief concedes, a publication by Stocks et al found a correlation between bacterial colony-forming-units

[143] Def. Mot. at 34.
[144] Ex. 43 (Buck Report).
[145] *Id.*
[146] Def. Mot. p. 35-36.
[147] Ex. 43 (Buck Report).

(CFUs) and particles greater than 10µm.[148] As described in this brief, those particles can and do carry CFUs, and 3M has used particles as a proxy for bacteria in its own published studies.

As the Comments to Rule 401 make clear, ñA brick is not a wall.ò (internal citation omitted). Buckôs testing is a ñbrick,ò just one piece in the evidentiary wall in this MDL. It is relevant under Rule 401 even if it does not attempt to fully resolve the ultimate question of whether Bair Hugger causes DJI.

Defendants have argued and continue to argue that Bair Hugger has a filter that is sufficiently efficient to avoid ejecting bacteria-laden particles. Buckôs testing shows that Bair Hugger emits particles, including particles of the size known to carry CFUs.[149] Plaintiffs argue that Bair Hugger causes such particles to migrate to the surgical site and cause infections. The jury will more easily be able to understand the flaws in Defendantsô defenses having heard about Buckôs testing. Thus, it ñfitsò this case for *Daubert* and Rule 401 purposes.

Other evidence, including that evidence cited above, shows that certain particles, including particles of the size identified by Buckôs testing, can carry bacteria.[150] Additional evidence, including the LES simulation performed by Dr. Elghobashi, shows that a statistically significant number of 10µm particles are mobilized by Bair Hugger and

[148] Defendantsô Motion at 35-36.
[149] Ex. 43 (Buck Report).
[150] *See* Plaintiffsô Response to Defendantsô Objection to Medical Causation Experts.

transported to the surgical site.[151] When considered in the context of that additional evidence, Buckôs testing and opinions increase the likelihood that Bair Hugger caused an infection by emitting bacteria-laden particles that migrate into the surgical site.

Defendants offered no explanation for their claim that Buck fails the Daubert ñfitò requirement. To the extent Defendantsô argument is predicated on Buckôs particle counts instead of bacterial counts, it fails for the same reasons as described above. The rules of evidence permit an expert to offer testimony on an intermediate fact. For example, in *Bonner*, the court excluded an expertôs opinion on the ultimate issue (chemical exposure caused permanent Parkinsonian symptoms), but admitted the expertôs opinion on an intermediate fact (exposure caused plaintiffôs acute symptoms). 259 F.3d at 931.

Defendantsô criticism of Buck boils down to Defendantsô insistence that he could have performed a different test. That is irrelevant. Had Michael Buck attempted to perform the test Defendants now suggests, Defendants would be shouting from the rooftops that Buck is not a bacteriologist and therefore not qualified to perform that test. Plaintiffs should not be penalized for keeping their expert opinions within their respective areas of expertise.

IV. CONCLUSION

Each of Plaintiffsô engineering experts has impeccable credentials in their respective fields. Each is qualified to offer the testimony and opinions in their respective reports. Each of Plaintiffsô experts followed reliable, established methodology in reaching

[151] *See* Ex. 4 (Elghobashi Rep.).

the conclusions and opinions offered in this litigation. For the reasons stated above, Defendantsô attempt to exclude the testimony from Plaintiffsô engineering experts must be denied.

Respectfully submitted,

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